



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/024,433 | 12/18/2001 | Robert G. Korneluk | 07891/018003 | 3050 |

21559 7590 05/17/2004

CLARK & ELBING LLP
101 FEDERAL STREET
BOSTON, MA 02110

| |
|----------|
| EXAMINER |
|----------|

KAUSHAL, SUMESH

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1636

DATE MAILED: 05/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SUPPLEMENTAL ACTION
Notice of Allowability

Application No.

10/024,433

Examiner

Sumesh Kaushal Ph.D.

Applicant(s)

KORNELUK ET AL.

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 10/6/03.
2. ☒ The allowed claim(s) is/are 5, 8, 15 and 16.
3. ☒ The drawings filed on 12/18/01 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
 - * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
 - (a) ☐ The translation of the foreign language provisional application has been received.
6. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No. _____.
 - (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
 - (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the margin according to 37 CFR 1.121(d).

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 5 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6 <input type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 3 <input type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No. _____ | 7 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |


JEFFREY FREDMAN
PRIMARY EXAMINER

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Kristina Bieker-Brady on 12/16/03 and 05/12/04.

The application has been amended as follows:

IN THE CLAIMS

Claims 1-4, 6-7 and 9-14 were canceled.

Claim 5 (Currently amended).

A method for identifying a compound that modulates inhibition by Testis IAP (TIAP), said method comprising the steps of:

(a) providing an isolated polypeptide having at least 95% amino acid identity to human TIAP (SEQ ID NO: 2), wherein the polypeptide comprises a BIR domain and inhibits apoptosis;

(b) contacting said TIAP polypeptide with a candidate compound; and

(c) detecting binding between said candidate compound and said TIAP polypeptide, wherein a candidate compound that binds said TIAP polypeptide is identified as a compound that modulates inhibition of apoptosis by TIAP.

Claim 8 (Currently amended).

The method of claim 5, wherein said TIAP polypeptide has the sequence of SEQ ID NO: 2.

IN THE SPECIFICATION

Page 1, line 6, -- now U.S. Patent No. 6,331, 412, -- was inserted before "which claims benefit".

Page 20 the text of lines 11-18 was replaced with:

-- Alternatively, abnormal expression of TIAP in non-germline tissue may indicate a reduced level of expression of XIAP, or another apoptosis-inhibiting protein in that tissue. Such an individual may be tested for expression of XIAP or other apoptosis-inhibiting proteins (e.g., NAIP, HIAP-I, or HIAP-2) using a variety of methods and reagents, including those described in USSN's 08/511,485 (now US PN 5,919,912), 08/576,956 (now US PN 6,156,535), 60/017,354 (now abandoned), 60/030,590 (now abandoned), 08/844,693 (now US PN 6,159,948), 08/913,322 (now US PN 20020137028), and 08/800,929 (now US PN 6,133,437), and PCT applications PCT/1B97/00721, PCT/1B97/00142, and PCTSB96/01022, hereby incorporated by reference. --

REASONS FOR ALLOWANCE

The following is an examiner's statement of reasons for allowance:

Claims 5, 8 and 15-16 are allowed because the prior art of record does not suggest or teach a method for identifying a compound that modulates inhibition of apoptosis by Testis IAP (TIAP, encoded by the amino acid sequences of SEQ ID NO:2).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sumesh Kaushal Ph.D. whose telephone number is 703-305-6838 (**571-272-0769**). The examiner can normally be reached on Mon-Fri. from 9AM-5PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel Ph.D. can be reached on 703-305-1998 (**571-272-0781**). The fax phone numbers for the organization where this application or proceeding is assigned is **703-872-9306**. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

S. Kaushal
Patent examiner


JEFFREY FREDMAN
PRIMARY EXAMINER